WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Avenue, N.W.
Washington, DC 20036
202-588-0302

March 5, 2007

Re: Draft Guidance- In Vitro Diagnostic Multivariate Index Assays
Docket No. 2006D-0347

Dear Sir or Madam:

Please include in this docket the testimony I gave at FDA's February 8, 2007 public hearing. That testimony follows.

Sincerely,

/s/ Richard A. Samp

Richard A. Samp

FDA's Ill-Conceived Effort to Regulate Laboratory-Developed Tests

Richard A. Samp
Chief Counsel
Washington Legal Foundation
February 8, 2007

My name is Richard Samp. I am Chief Counsel of the Washington Legal Foundation, a public-interest law and policy center located in Washington, D.C. WLF devotes a substantial portion of its resources to improving health care delivery in this country. We believe that that goal can be best achieved if government regulators devote their energy to addressing proven hazards to public health while at the same time allowing medical professionals the freedom and flexibility to arrive at innovative solutions to our ever-changing health care needs.

WLF has no direct financial stake in the issues being addressed at today's public meeting. We have no connection with any of the laboratories whose tests FDA is proposing to regulate. If WLF has received financial support from any laboratory, it is negligible. I am testifying today because I am convinced that any FDA effort to impose significant regulation on laboratory-developed tests will be a setback for public health. My background is as a lawyer, not a medical professional. So I can speak with somewhat more confidence when I tell you my other reason for testifying today: I am convinced that FDA's proposed regulatory effort is contrary to law.

For those same reasons, WLF filed a Citizen Petition with FDA on September 28, 2006. The Citizen Petition requests that FDA determine that it will not attempt to regulate as "medical devices" any assays developed by clinical laboratories strictly for their in-house use. The petition was prepared independently of FDA's September 7, 2006 draft guidance and raises several legal issues not addressed in the draft guidance. The Citizen Petition docket is open, and we encourage those with any interest in the issues addressed today to file comments in that docket.

Because I do not claim expertise as a medical professional, I will only briefly describe why I view laboratory-developed tests (or LDTs) as so important, and why FDA's proposed regulation could significantly hinder effective development and use of LDTs. Well over a thousand different tests are being used every day by clinicians to better inform diagnostic and therapeutic decisions. When new infectious agents first appear and a new diagnostic test is urgently needed for patient care, it is generally an LDT, not an FDA-approved or cleared device, that first meets that medical need. For patients with cancer, LDTs have entered wide clinical use in helping to manage their

care. Moreover, while inaccurate tests have the potential to cause health care problems, there is no evidence to suggest that currently available LDTs are inaccurate, and clinical labs are already subject to regulation by CMS under CLIA. If the system is not broken, it is difficult to understand why FDA feels such a compelling need to try to fix it.

Moreover, it is plain to anyone with an understanding of clinical labs that requiring them to go through FDA's pre-market review process and comply with FDA's device regulatory rules would have a crippling effect on their ability to continue to provide access to LDTs. Laboratories are not operated as medical device manufacturers. Although they must comply with CLIA, they do not maintain the procedures and documents for compliance with FDA's Quality System Regulation (QSR). Nonetheless, FDA is now asserting that labs are subject both to the QSR and to the adverse event reporting regulation. Labs are being told that they will have to figure out for themselves how procedures developed for device manufacturers would apply to them. Yet I don't know anyone who knows how one would go about retrospectively developing design history files, as required by the QSR. Food and drug law attorneys are unanimous in concluding that these and other medical device regulations will preclude many tests from being offered at all. Labs constantly innovate and improve their tests; the need to comply with FDA regs would prevent many of these changes from being made, and severely inhibit the flexibility of laboratories and their ability to meet clinicians' needs, *e.g.*, identifying rapidly changing pathogens such as SARS and HIV. Moreover, if (as is likely) FDA regulation requires many existing tests to be labeled "investigational," patients' ability to obtain reimbursement for these often expensive tests will be thrown into doubt – many insurers balk at paying for procedures deemed "investigational."

I recognize that FDA may be reluctant to heed medical advice from the Washington Legal Foundation. But I ask you to heed our legal advice: the regulation of LDTs proposed by the Draft Guidance is contrary to law. I have three grounds for that conclusion, all spelled out in more detail in our Citizen Petition. First, Congress has spoken, and it has allocated the requisite regulatory authority to CMS under CLIA, not to the FDA under the Medical Device Amendments of 1976. Second, the Secretary of HHS confirmed in 1992-93 that the regulatory authority lies with CMS. Third, even if FDA does possess authority to begin to regulate LDTs as medical devices, it is going about doing so in a manner that violates the Administrative Procedure Act (APA).

The only congressional legislation directed specifically at laboratories is CLIA, a 1988 statute whose enforcement responsibilities have been assigned to CMS. CLIA establishes quality standards for virtually all clinical laboratory testing. Clinical labs that offer LDTs fit to a "T" the type of facility that Congress said should be regulated under CLIA: "a facility for the biological, microbiological . . . pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings." 42 U.S.C. Sec. 263(a).

In contrast, the 1976 Medical Device Amendment, under which FDA claims regulatory authority, does not have anything at all to say about laboratories or lab testing. Nor is there anything in the MDA's legislative history to suggest that Congress intended to grant FDA authority to regulate labs. Nor is there any evidence that in the years immediately following adoption of the MDA, FDA understood the law as granting such authority. It was not until the 1990s that FDA first began to suggest that it might possess

regulatory authority over labs offering LDTs, and it is only in the past year that FDA has sought to exercise its alleged authority. Under those circumstances, it is simply not credible to suggest that Congress did, indeed, intend in 1976 to grant FDA its newly discovered regulatory authority. It is theoretically possible, of course, that Congress, in adopting the MDA and CLIA, intended to create parallel regulatory schemes, each with independent authority over lab testing. But such an intent is highly implausible when one considers that the MDA said nothing about lab tests, while 12 years later CLIA specifically mandated regulation of lab tests without once suggesting that a pre-existing statute provided for a more elaborate set of regulations. In the absence of authority from Congress, FDA's recent attempts to regulate lab tests are improper and should cease.

Second, even if the statutory language were deemed ambiguous, subsequent actions by the Secretary of HHS remove any doubt that FDA lacks authority to act. It is the Secretary – not any of his subordinate agencies – that possess the authority through lawful rulemaking to decide where the authority to regulate clinical labs should lie. The Secretary made that decision in 1992-93 when he approved comprehensive CLIA regulations that assigned regulatory authority to CMS. In February 1992, final regulations took effect that set forth (and I quote) "*all* requirements applicable to clinical laboratories engaged in testing in interstate commerce." The final regulations adopted in January 1993 established (and again I quote) "*uniform* requirements" to ensure the quality of lab services. CLIA regulations underwent extensive revision in 2003, and again there was no acknowledgment of any FDA role in regulating LDTs. The Secretary's approval of those regulations is wholly inconsistent with FDA's argument

that it possesses the authority to impose a regulatory regime that would void huge parts of the existing CLIA rules.

Third, even if FDA really did possess the regulatory authority it now asserts, it is attempting to assert that authority in a manner that violates the APA. Although FDA has quietly said for about a decade that it possesses regulatory authority, it never attempted to exercise that authority until the past year. It is not the character of LDTs that has changed; it is FDA policy that has changed. Before a federal agency may change policies in a manner that "materially changes established burdens and benefits," it must comply with formal APA notice-and-comment procedures. This, FDA has failed to do. The APA was adopted for a very good reason: to ensure that agencies do not adopt new substantive policies until after all interested stakeholders have had a full and fair opportunity to weigh in on the proposed changes and until after the agency has carefully considered their concerns. One would hope that FDA would comply with the APA without having to be ordered by a court to do so.

Finally, I want to very briefly raise First Amendment concerns I have with FDA's assertion of regulatory authority. When a lab professional provides a physician with test results, he or she is communicating medical information that FDA has no reason to believe is untruthful. Even if FDA asserts that such communication should be deemed "commercial" speech, it is still entitled to a substantial degree of First Amendment protection. Before FDA gets into the business of regulating such speech, it ought to think long and hard about whether its regulatory objectives are sufficiently compelling to justify government impairment of free speech rights in this manner.

Thank you for the opportunity to share my views with you today.